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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

COLLEEN JAEGER, et al., Plaintiffs, v. **HOWMEDICA OSTEONICS CORP.**, Defendant.	Case No. 3:15-cv-164-HSG Judge: Hon. Haywood S. Gilliam, Jr. **SECOND AMENDED COMPLAINT WITH JURY DEMAND**

Plaintiffs Colleen Jaeger and William Jaeger, for their Second Amended Complaint against Defendant Howmedica Osteonics Corp., aver and state:

I. Parties

1. Plaintiff Colleen Jaeger is an individual and is a citizen of the State of California.

2. Plaintiff William Jaeger is an individual and is a citizen of the State of California. Mr. Jaeger is the spouse of Ms. Jaeger.

3. Defendant Howmedica Osteonics Corporation is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in Mahwah, New Jersey.

4. Defendant Howmedica Osteonics Corporation is a wholly-owned subsidiary of Stryker Corporation.

5. Defendant Howmedica Osteonics Corporation regularly conducts business throughout the United States—including in the state of California—directly and through its wholly-owned subsidiaries.

6. Defendant Howmedica Osteonics Corporation does business as "Stryker Spine" and is hereinafter referred to as "Stryker Spine."

II. Nature of the Action

7. This is an action for damages suffered by Plaintiffs Colleen Jaeger and William Jaeger and caused by a medical device known as CerviCore.

8. Stryker Spine owned, developed, designed, tested, licensed, manufactured, and marketed the CerviCore device and conducted a human clinical trial of the device in approximately 260 subjects.

9. Stryker Spine subcontracted the manufacture of the 260 CerviCore units used in the clinical trial to several component part manufacturers, including Hammill Manufacturing Company.

10. Ms. Jaeger participated as a subject in the CerviCore clinical trial and had a CerviCore unit installed in her cervical spine.

11. Stryker Spine and Hammill Manufacturing manufactured the CerviCore unit implanted in Ms. Jaeger's cervical spine.

12. The CerviCore devices are faulty, dangerous, or defective and have sickened Ms. Jaeger, caused her pain and suffering, medical costs, lost wages, loss of enjoyment of life, and other damages.

13. As a result, Ms. Jaeger and Mr. Jaeger suffered extensive damages.

III. CerviCore Background

A. The SpineCore Acquisition

14. The CerviCore product was initially developed by a company called SpineCore, Inc.

15. In 2004, Stryker Corporation purchased SpineCore for $120 million in cash plus promises of up to $240 million more in milestone payments when CerviCore and the other SpineCore product (FlexiCore) gained FDA approval and were launched commercially.

16. Stryker transformed the former SpineCore and its two products into a division of Stryker's wholly-owned subsidiary, Defendant Howmedica Osteonics Corporation, and called the former SpineCore group the "Stryker Spine Motion Preservation Unit."

17. Stryker Spine' MPU group was comprised of former SpineCore employees. Stryker Spine installed J.P. Errico—who was one of the inventors of CerviCore as well as one of the founders of SpineCore—as the head of the MPU.

18. As part of its acquisition, Stryker Spine also incorporated Dr. Thomas Errico—another CerviCore inventor and SpineCore founder—as a consultant to Stryker and its MPU.

19. Stryker Spine's MPU then designed, redesigned, marketed, and conducted a clinical trial of the CerviCore disc.

B. The CerviCore Device

20. CerviCore is an artificial cervical disc system that is implanted between two cervical vertebrae. It was developed as an alternative to anterior discectomy and fusion (ACDF) procedures, which have been a common treatment for patients with degenerated or herniated cervical discs.

21. The CerviCore device has an upper and lower plate that articulate (that is, the plates form a joint by moving against each other). The device does not attach with screws; each plate has teeth meant to engage the vertebrae above or below the unit:

22. Stryker Spine portrayed CerviCore as advantageous over ACDF fusion surgeries, claiming CerviCore's articulating surfaces would afford the patient range of motion where fusions, by their nature, limit motion.

23. Stryker Spine designed the CerviCore to be manufactured from bars made of a medical-grade mix of the metals cobalt, chromium, and molybdenum.

24. Stryker Spine designed the CerviCore's articulating surfaces—that is, the surfaces that move against each other—to be polished to a mirror-like finish.

25. Stryker Spine designed the remainder of the CerviCore's surfaces—that is, the surfaces other than those that move against each other, including the surfaces that come in contact with the recipient's body—to be left unpolished and coated with a thin spray of pure titanium.

C. Regulatory Hurdles

26. To capitalize on its $120 million to $360 million investment in SpineCore, Stryker Spine had to bring the two devices it purchased from SpineCore—the CerviCore and FlexiCore—to market commercially.

27. Because FDCA Regulations classify the CerviCore as a "Class III" medical device (see 21 C.F.R. § 860.93), to bring the product to market, Stryker Spine needed FDA "Pre-Market Approval" (PMA):

> Class III means the class of devices for which premarket approval is or will be required in accordance with section 515 of the act. A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls described in paragraph (c)(2) of this section would provide such assurance and if, in addition, the device is life-supporting or life-sustaining, or for

> a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

21 C.F.R. § 860.3(c)(3).

28. Before the FDA would grant Pre-Market Approval for CerviCore, Stryker Spine had to conduct a successful human clinical trial. It could not start such a trial, however, until the FDA approved an "Investigational Device Exemption" (IDE) that would allow implant of the device in a limited number of patients during a human clinical trial.

29. Stryker Spine applied for IDE approval for CerviCore. The FDA said "no."

30. Stryker Spine applied again. Again, the FDA said "no."

31. In response to multiple FDA rejections, Stryker Spine scrapped the plan for the device as it bought it from SpineCore and redesigned it within a very short time. It then told the FDA the changes were minor, yet, the original and modified devices bear little resemblance to each other:

Original design	**Modified design**
(as created by its designers)	(as implanted in Ms. Jaeger's spine)
Rejected twice by the FDA	Flanges removed to address the FDA's concern over the quantity of titanium
	

32. At this point, Stryker Spine says it got FDA approval to begin a clinical trial. This is a debatable point, particularly with the last-minute change-up to the device (and, any murkiness as to this question is itself a bad sign; regulatory approval is not nebulous). In any case, Stryker Spine, through its Study Investigators such as Dr. James G. Zucherman, MD, started installing devices in patients.

IV. Ms. Jaeger's Enrollment in the Clinical Trial and CerviCore Implant

33. Plaintiff Colleen Jaeger received a CerviCore device as part of the CerviCore clinical trial.

34. Ms. Jaeger had previously injured her cervical spine by moving furniture that was too heavy. She was diagnosed with a rupture of the C5/C6 cervical disc and endured pain and discomfort as she tried non-surgical remedies.

35. Nevertheless, there came a point where non-invasive remedies for Ms. Jaeger's injury would not be sufficient and Ms. Jaeger consulted with the spinal neurosurgery group that included Dr. Matthew D. Hannibal, MD and Dr. James F. Zucherman, MD about her options.

36. Drs. Hannibal and Zucherman are neurosurgeons specializing in spinal surgeries. At the time, both were CerviCore Study Investigators (Dr. Zucherman the lead investigator for the site and Dr. Hannibal a co-investigator), meaning they were two of the surgeons who had enrolled in the clinical trial.

37. Dr. Hannibal diagnosed Ms. Jaeger with a "large C5-6 left paracentral disc herniation with partial compression of the left side of the spinal cord and exiting nerve root," and also noted "a mild loss of normal cervical lordosis."

38. Dr. Hannibal told Ms. Jaeger about the CerviCore, explained that she may qualify as a candidate for the study, and told her that if she elected to join the study, she would have a 50% chance of receiving the CerviCore unit and an equal chance of receiving the control surgery—the more conventional ACDF.

39. Dr. Hannibal presented Ms. Jaeger with the materials he had received from Stryker Spine, including a brochure and the informed consent agreement.

40. Ms. Jaeger agreed to participate in the clinical trial, and, on May 23, 2006, underwent surgery. She was selected to receive the CerviCore unit (as opposed to the control group surgery).

41. Ms. Jaeger's implant surgery was successful in every way; Dr. Hannibal noted no problems.

42. Two weeks post-surgery, Dr. Hannibal noted: "she is off pain medications, her left arm [has] some very minimal residual numbness in the fingertips, she is pleased with her result at this

time; [X-Rays] taken today show that the prosthesis remains in optimal position and she remains in optimal alignment of the cervical spine."

V. Conduct of the Human Clinical Trials

43. Each person, like Ms. Jaeger, who was implanted with a CerviCore device, was part of the human clinical trial and his or her health was to be monitored for eight years. (Initially, Stryker Spine set up the CerviCore clinical trial as a two-year study, but sought and received FDA approval to extend it to five years, then again to extend it to eight years.)

A. Study Structure

44. In total, approximately 260 people have received CerviCore units in the United States: 200 patients were implanted with CerviCore units as part of the initial "Pivotal" CerviCore human clinical trial. Another 60 patients were implanted in the second and final phase (the "Continued Access" phase).

45. Stryker Spine conducted its CerviCore human clinical trial in twenty "Study Sites" around the United States, including the site at which Ms. Jaeger was treated: St. Mary's Medical Center.

46. In each Study Site, Stryker Spine recruited one to four physicians—generally neurosurgeons who regularly performed spinal surgery—to act as "Study Investigators" by implanting the device in their patients and monitoring those patients during the course of the study.

47. In the process of recruiting Study Investigators and Study Sites, Stryker Spine provided the Study Investigator physicians—including Ms. Jaeger's physician, Dr. James G. Zucherman, MD—with detailed CerviCore information, including:

a.) descriptions of the device;

b.) statements and promises about the device;

c.) statements and promises about how Stryker Spine would conduct the human clinical trial;

d.) statements and promises about how Stryker Spine would keep its Study Investigators informed of developments in the clinical trial and new information about the CerviCore device; and,

e.) information about the device's known dangers and potential dangers.

B. Clinical Trial Progress

48. According to Stryker Spine, the CerviCore clinical trial went relatively well for a few years (although, Stryker Spine concludes this only after discounting a few highly disturbing instances of device migration and shifting).

49. The clinical trial's primary endpoint was an increase in range of motion as compared with the control (fusion) surgery. Stryker Spine had proposed that the CerviCore's ability to articulate (that is, move as a joint does) would, as compared to a fusion surgery, provide the patient with no loss in range of movement of his or her neck.

50. The clinical trial showed the CerviCore device met its primary endpoint very well; patients with the device had a statistically significant greater range of motion than their counterparts who received the ACDF.

C. Ms. Jaeger's Clinical Trial Progress

51. Ms. Jaeger's initial progress resembled the overall study progress.

52. Nevertheless, as Ms. Jaeger saw Dr. Hannibal for follow-up visits, Dr. Hannibal noted that the CerviCore did not cure all Ms. Jaeger's prior problems:

a.) At the nine-month visit, Dr. Hannibal noted Ms. Jaeger had ongoing pain and headaches, but that the CerviCore was in "optimal position" and unchanged.

b.) At the one-year visit, Dr. Hannibal only minimal pain.

c.) At two years, Dr. Hannibal wrote to Ms. Jaeger's primary care physician that she was "doing well, not currently taking any pain medications, and has resumed normal activities." He also noted proper placement of the implant per the images taken.

53. Dr. Hannibal left St. Mary's (unrelated to the subject of this suit) and Ms. Jaeger began seeing the lead Study Investigator, Dr. James F. Zucherman in late 2008.

54. In November 2008, Dr. Zucherman wrote: "Mrs. Jaeger fell three months ago, landing face down and striking her head on a concrete floor. For the last three months, she has been having neck pain with radiation down into the right shoulder and arm, with numbness and tingling as well." Regarding the CerviCore unit, he noted: X-rays were done today and show the cervical arthroplasty implants are intact. No abnormalities are noted."

D. Ms. Jaeger's Metal Ion Test Results and Stryker Spine's Cover-Up of Their Significance

55. Within the 260-person CerviCore population, Stryker Spine elected to enroll just 30 CerviCore recipients in what it termed a "Metal Ion Substudy" and monitor their blood metal levels to see if their CerviCore devices caused increases in blood metal levels.

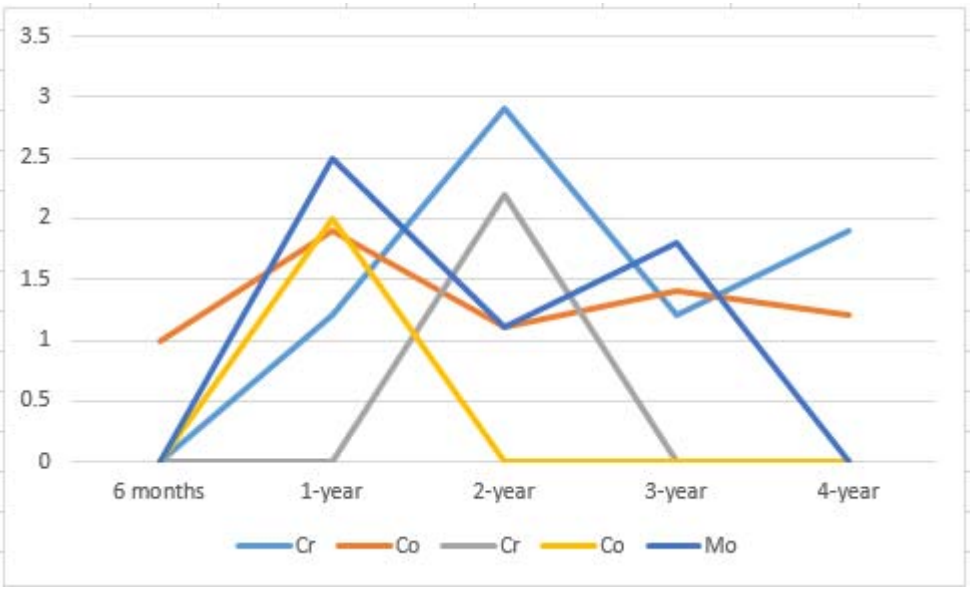
56. Ms. Jaeger was fortunate enough to receive this monitoring.

57. Nevertheless, it appears that Stryker Spine failed to take a baseline blood metal ion reading for Ms. Jaeger.[1]

[1] Stryker Spine has produced the blood metal test results for Ms. Jaeger and those include no test prior to November 2, 2006 (which is six months after her index surgery). Furthermore, in analyzing and interpreting the results of the metal ion study for the FDA and Study Investigators, Stryker Spine notes it failed to collect a pre-surgery baseline sample for one subject (although it does not say that subject was Ms. Jaeger, but the failure to produce the result indicates it must be her).

58. Without a baseline reading, Ms. Jaeger's test results reveal an unclear picture:

Time	Cr (ICP/MS)	Co (ICP/MS)	Cr (GFAAS)	Co (ICP/MS)	Mo (ICP/MS)
6 months	None	1.0	None	None	None
1-year	1.2	1.9	None	2.0	2.5
2-year	2.9	1.1	2.2	None	1.1
3-year	1.2	1.4	None	None	1.8
4-year	1.9	1.2	None	None	None



59. In October 2008 (about two-and-a-half years after Ms. Jaeger received her CerviCore), Stryker Spine sent Dr. Zucherman the CerviCore annual report, and, within the "Risk Analysis" section assured Dr. Zucherman:

> while there is evidence that the levels of chromium and cobalt in serum and urine may be slightly to moderately elevated (~1.1µg/L) in subjects with metal-on-metal implants and *in vitro* tests demonstrate adverse cellular responses, there continues to be no published long term human studies associating cobalt and chromium with increased risk for any significant health problems.

60. Around this same time, Ms. Jaeger first raised a question about the blood metal tests being conducted on her yearly: Although Dr. Zucherman's records do not reflect it, Ms. Jaeger recalls

asking Dr. Zucherman for the results of her blood metal tests, which would be—at the soonest—in November 2008.

61. Dr. Zucherman provided the results, but, consistent with Stryker Spine's claims that "slightly to moderately elevated" chromium and cobalt levels were not a concern, Dr. Zucherman indicated no problem with Ms. Jaeger's CerviCore.

62. In October 2009, Stryker Spine reinforced its prior year claim, assuring Dr. Zucherman:

> A review of the full articles was done and no new increased risks were identified for cervical spine arthroplasty or health effects of metal ions through this process.

63. The next time Dr. Zucherman saw Ms. Jaeger after this report (April 2010), he noted the implant was just fine: "proper alignment. No abnormality noted. No instability is seen, and no mass or fraction is seen on the x-rays."

64. The October 2010 report from Stryker Spine claimed:

> Average cobalt, chromium and molybdenum ion concentrations in the blood of CerviCore and fusion subjects is below normal limits (maximum values may slightly exceed the normal limit both pre- and post-operatively, refer to Table 17).[2]
>
> Based on this review there are no new or increased risks to subjects that should be identified.

65. Trusting Stryker Spine's meta-analysis of the overall blood metal ion data, and considering that Ms. Jaeger's results were under what Stryker Spine said were values slightly exceeding the normal limits, but still not a concern, Dr. Zucherman did not raise any concern about metal ion exposure in Ms. Jaeger's late 2010 visit.

66. The October 2011 annual CerviCore report to Dr. Zucherman repeated the precise language, claiming maximum values slightly exceeding normal limits are not a cause for a new or increased risk.

67. A few weeks after it sent Dr. Zucherman this report, though, Stryker Spine finally gave up on trying to obtain commercial approval for the doomed device and requested the FDA allow it to close down the CerviCore clinical trial.

[2] Table 17 contains maximum values of 3.3 for cobalt and 5.6 for chromium, both of which Ms. Jaeger is under.

68. In June of 2012, Stryker Spine provided Dr. Zucherman with what the company had hoped would be the final IDE report. That report repeated Stryker Spine's quotes downplaying the metal debris concerns: "Average cobalt, chromium and molybdenum ion concentrations in the blood of CerviCore and fusion subjects is below normal limits (maximum values may slightly exceed the normal limits both pre- and post-operatively, refer to Table 17)."[3]

69. Finally, with mounting evidence of a concern, the FDA rejected the June 2012 report and forced Stryker Spine to tell the truth about the growing indications its device may be harming people. The FDA said::

> The study close-out materials provided to patients and investigators (Appendix F) . . . do not fully disclose all risks potentially associated with metal-on-metal articulating implants.
>
> * * *
>
> In the letter "Post Closure Follow Up Procedures," you state that there were "no instances of delayed metal hypersensitivity" in the CerviCore investigations. While it is true that no cases have been confirmed, a further review of the information available on the patients with adverse events and device explants may suggest a potential Adverse Local Tissue Reaction (ALTR) consistent with those reported in the literature for other cervical and lumbar implants and Metal-on-Metal total hip replacements. We suggest the wording in this paragraph be revised to state that there were some possible cases of ALTR similar to what has been reported in the literature.

70. On September 13, 2012, at the FDA's insistence, Stryker Spine returned to Dr. Zucherman and revised its prior claims:

> Although no instances of delayed metal hypersensitivity have been observed in any of the CerviCore investigations, some information regarding patients who have reported adverse events and have had devices explanted **may suggest a potential Adverse Local Tissue Reaction (ALTR) consistent with events reported in some literature relating to other cervical and lumber implants and Metal-on-Metal total hip replacements.** We also ask that you report information indicative of any such potential reactions (e.g., delayed pain; painful swelling; skin conditions such as eczema, dermatitis, etc. without other attributable cause; muscle tumors and muscular necrosis; metallosis; periprosthetic fibrosis; delayed neurologic symptoms; delayed wound healing; etc.).

(emphasis added).

[3] Once again, Ms. Jaeger's values were above the thresholds, but way below what Stryker Spine called the values that "slightly exceed the normal limits."

71. Dr. Zucherman next saw Ms. Jaeger 25 days later on October 8, 2012. At that time, he decided the device should be explanted (although he attributed it, at least in part, to a recent fall Ms. Jaeger suffered).

72. Dr. Zucherman removed the failed unit on November 6, 2012. He sent the CerviCore device and a tissue biopsy for analysis, and that analysis determined:

> MICROSCOPIC DIAGNOSIS:
>
> A. CERVICAL SPINE, PERI-IMPLANT TISSUE, BIOPSY –
>
> --DENSE FIBROUS TISSUE SHOWING CHRONIC REACTIVE CHANGES INCLUDING FOCAL GIANT CELL REACTION AND PIGMENTED MACROPHAGES, CONSISTENT WITH METALLOSIS (SEE COMMENT)

73. At a post-removal follow-up visit shortly thereafter, Dr. Zucherman shared these results with Ms. Jaeger.

E. Stryker Spine's Concealment of the Clinical Significance of the Metal Ion Substudy Data

74. Study Investigators, such as Dr. Zucherman, have only a few patients and must rely on both the data collected by the Study Sponsor (Stryker Spine) and the analysis of those data.

75. While Stryker Spine provided Study Investigators, such as Dr. Zucherman, with raw data on the 30 patients in whom it monitored blood metal levels, it withheld the clinical significance—that is, the analyses that would help the Study Investigator determine if their patients were likely suffering from metallosis—from Dr. Zucherman and the other Study Investigators (as well as from Ms. Jaeger, of course).

76. In 2011, Stryker Spine Study Investigator Dr. Jeffrey Fischgrund testified in a deposition on Stryker Spine's behalf in litigation between CerviCore's inventors and Stryker Corporation.

77. Dr. Fischgrund's testimony indicated Stryker Spine did not provide its Study Investigators with the clinical significance of the metal ion substudy data:

> Q Do you have an understanding as to what the CerviCore metal ion study was?

> A I know there was a substudy -- that did not involve my patients -- looking at the metal ion release, but I don't really know much about the details of the final -- the results.
>
> Q Do you know who conducted that study?
>
> A I imagine it would be Stryker, but I don't know which investigators were involved. I'm almost certain it was not my patients, though.
>
> Q Do you know what the study ultimately concluded?
>
> A You know, that's one of the few things that I reread within the past week or two, and I know there were numbers. That there were ions. I just don't know how to put them in context, so I couldn't tell you the clinical significance of them.

78. On information and belief, the analysis of the metal ion substudy data shows the clinical significance (that is, the analysis shows a statistical increase in blood metal ion levels to the point that it could affect patients' health).

79. On information and belief, Stryker Spine not only withheld the metal ion substudy data, analysis, and significance from Dr. Fischgrund, but also from all Study Investigators, including Dr. Zucherman.

80. Dr. Zucherman and Ms. Jaeger's other physicians could have used the metal ion substudy data, analysis, and significance to provide better care to Ms. Jaeger and Stryker Spine's decision to not conceal these (particularly after learning of its manufacturing defect) diminished Ms. Jaeger's physicians of the ability to provide informed care to Ms. Jaeger.

F. Off-Label Conduct

81. As detailed throughout, Stryker Spine hastily changed CerviCore's design to eliminate the fixation screws to be inserted in the vertebrae above and below the unit:

Original design	Modified design
(as created by its designers)	(as implanted in Ms. Jaeger's spine)
Rejected twice by the FDA	Flanges removed to address the FDA's concern over the quantity of titanium
	

82. Stryker Spine made this design change to appease the FDA's concerns about the quantity of Titanium in the device (the original screws were made of Titanium; removing them reduced the total Ti weight).

83. Hammill Manufacturing assisted in designing and testing the revised device and seeking FDA approval to make the last-minute change.

84. Very early in the human clinical trial, Stryker Spine had instances of spontaneous device migration, including the Angela Moneymaker event. See Paragraphs 169, 170, *supra*.

85. Rather than stop the study because dangerous events were occurring, and rather than seek FDA involvement, Stryker Spine used its sales force to tell Study Investigators, including Dr. Zucherman, that they should modify their surgical technique to encourage quicker device fixation and bony ingrowth.

86. In one such instance, Stryker Spine released "Rolando's Rules," a "helpful" set of off-label tips and tricks that changed the surgical technique. It propagated these through its sales and clinical channels rather than through the proper communication channels (that is, the channels used to communicate FDA-approved changes).

87. Propagating a surgical technique without FDA approval or, worse, in contravention to FDA approval is "off-label" conduct and is illegal for a medical device manufacturer.

88. Furthermore, changing the surgical technique without regulatory approval voids the purpose of the human clinical trial, which was to test the efficacy and safety of the device without making secret, off-label adjustments.

89. Furthermore, changing the surgical technique without regulatory approval voids any informed consent patients may have given.

90. Furthermore, many CerviCore recipients show indications of spontaneous and unexplained osteophytes and other bone growth that could be consistent with Stryker Spine's off-label, unapproved modifications to the CerviCore surgical technique made to reduce the instances of device migration.

91. For example, Ms. Jaeger, had to be revised because, among other things, she developed a large bone mass that grew from the area of her CerviCore and pushed against her esophagus. Likewise, fellow CerviCore study participant Phyllis Ann Good, was found to have a boney growth (osteophyte) at the C5 vertebrae, which is one of the two vertebrae that abuts her CerviCore implant. *Good v. Howmedica*.

VI. Manufacturing Defects

92. Stryker Spine (through its employees and SpineCore, the company it purchased and integrated into itself) was entirely responsible for the design and manufacture of the CerviCore units.

93. Stryker Spine contracted with Hammill Manufacturing to manufacture CerviCore devices during the clinical trial.

A. Specific Manufacturing Defects in Lot #00105 Related to Diametral Clearances

94. Hammill Manufacturing—as a subcontractor of Stryker Spine—manufactured Ms. Jaeger's CerviCore and manufactured the other 259 CerviCore units.

95. Ms. Jaeger's unit was manufactured on or about on or around November 1, 2005 as part of Lot #00105, which was one of 36 lots made by Hammill for Stryker Spine.

96. Manufacturing records now reveal the following about Lot #00105:

a.) Lot #00105 included 30 upper and lower baseplate units.

b.) Measurements of the dimensions of the **upper** units in Lot #00105 reveal 95.2% contained an out-of-tolerance measurement. That is, 95.2% of the upper plates made in this batch do not meet specifications in that their part measurements are outside the allowable +/- tolerance as designed.

c.) Measurements of the dimensions of the **lower** units in Lot #00105 reveal 100% contained an out-of-tolerance measurement. That is, 100% of the lower plates made in this batch do not meet specifications in that their part measurements are outside the allowable +/- tolerance as designed.

d.) The most common and persistent deviations from specifications relate to the articulating surfaces: Hammill was not able to consistently make CerviCore parts that had in-specification radii of the curved surfaces and in-specification profiles of the curved surfaces.

e.) The units' design calls for these two surfaces to rotate against each other as the recipient's vertebrae rotate.

f.) Specifications failures of these very measurements will cause—and, in fact, did cause—the units to generate more wear debris as those two surfaces articulate against each other.

B. <u>Specific Manufacturing Defects in Lot #00105 Related to Surface Polish</u>

97. Furthermore (and apparently unrelated to the issue of the diametral clearance), manufacturing records now reveal anomalies in the articulating surface polishing process for CerviCore devices in Lot #00105.

98. The design of the device calls for the two articulating surfaces to be polished to an extremely fine, mirror-like finish.

99. The surface polish of the articulating surface is key to reducing the generation of metal wear debris; the smoother the finish, the less wear debris generated.

100. Lot #00105's manufacturing records indicate Hammill Manufacturing did not properly measure and record the surface polish according to the inspection plan; instead of recording the value from a profilometer or perthometer (devices that measure the roughness of a surface finish), Hammill marked 100% of the parts it made "AC" (acceptable).

101. In late 2007, Stryker Spine issued an RMA and returned the unused portions of every batch of CerviCore parts to Hammill Manufacturing with the instruction to remake or rework the articulating surfaces.

102. Nevertheless, that rework of the articulating surface polish was related to Stryker Spine's attempts to obtain commercial approval from the FDA; Ms. Jaeger's CerviCore was not reworked to fix its finish.

C. Specific Manufacturing Defects in Lot #00105, Related to the Titanium Plasma Spray Coating

103. Furthermore, and unrelated to the diametral clearance defects and the surface finish polish defects, Stryker Spine changed the vendor who was to apply the pure titanium plasma spray coating without FDA approval.

104. Much later, the FDA finally discovered the unapproved vendor change and, internally, Stryker Spine employees called it an oversight.

105. Manufacturing records for Lot #00105 indicate that the dimensions of the titanium coating were incorrect; when units returned from the newly-selected coating vendor, they had the wrong overall dimensions (indicating the coating was not applied properly).

106. Explant reports show instances of removed units with portions of the coating missing—indicating it sheared of and entered the patients' bodies.

D. Stryker Spine's Knowledge of—and Concealment of—the Manufacturing Defects

107. Manufacturing records for Lot #00105 reveal Hammill Manufacturing many (but, curiously, not all) of these manufacturing anomalies.

108. The associated travel tickets indicated Hammill very likely sent the records indicating these manufacturing anomalies to Stryker Spine.

109. Furthermore, Hammill Manufacturing's president and CEO has recently provided an affidavit indicating just that: he claims he told Stryker Spine there was a discrepancy between the machining capabilities and the part specifications and Stryker Spine told Hammill to make the parts nonetheless:

> In 2005, Hammill began production of certain CerviCore base plates that also appeared to be parts for development purposes. Those parts also consistently reflected the conflict between the proposed specifications, machining capabilities, and the inspection requirements.

110. Stryker Spine repeatedly represented to Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA that it had tested the rate of wear debris Hammill-manufactured CerviCore units shed and that the quantity of debris was negligible and safe.

111. Stryker Spine shared the alleged rate of wear debris generation in articles, in presentations, and in its IDE application (which it shared with Study Investigators and the safety monitoring departments within Study Sites).

112. Mid-way through the clinical trial, and after Ms. Jaeger had already received a CerviCore unit, Stryker Spine attempted to transition the manufacture of CerviCore units from the Hammill Manufacturing—which had manufactured all the units used in the clinical trial—to its own facility for the manufacture of units once it gained FDA approval to release CerviCore commercially.

113. Stryker Spine's facility tried to recreate the device according to the specifications Hammill Manufacturing allegedly used when it created Ms. Jaeger's CerviCore, but it could not recreate it.

114. Stryker Spine utilized its own Motion Preservation Unit personnel—the very people who had designed the product and had stewarded it through the manufacturing process—to try to recreate the device as Hammill Manufacturing said it created the device.

115. But, try as they might, Stryker Spine could not recreate a CerviCore device that performed the way Hammill Manufacturing claimed its device performed.

116. Following the precise protocols, drawings, and procedures, and with the assistance of the team that started the CerviCore process, Stryker's newly-created CerviCore devices shed four times the Cr-Co-Mo debris as the Hammill-manufactured device (that is, the one in Ms. Jaeger's cervical spine).

117. The FDA would not grant approval to a device shedding Cr-Co-Mo at this rate.

118. Unable to gain FDA approval, Stryker Spine eventually abandoned the CerviCore device and the hundreds of millions of dollars it invested in the device.

119. Further, unable to reconcile how it could not recreate the much lower wear rate allegedly observed in Hammill-manufactured devices, Stryker Spine eventually trained its focus on Hammill Manufacturing and accused Hammill of manufacturing CerviCore devices—including the CerviCore device in Ms. Jaeger's cervical spine—outside of specifications.

120. A reasonable manufacturer exercising ordinary care in manufacturing medical devices in general—and particularly in manufacturing devices to be used in a clinical trial—would not deviate from the design specifications.

121. Furthermore, manufacturing a medical device outside of the claimed or approved specifications renders the device misbranded and/or adulterated by FDA definitions.

122. Furthermore, it is a violation to recruit Study Investigators, such as Dr. Zucherman, by making certain representations about the medical device they are to surgically install and monitor, then knowingly or negligently not manufacture the device to those specifications or representations (or, at a minimum knowingly or negligently allow a device manufactured outside specifications to

be shipped to the St. Mary's Medical Center Study Site and implanted in Ms. Jaeger's cervical spine).

E. Stryker Spine's Communications Regarding the Defects

123. Stryker Spine knew of the defects in the articulating surfaces of the CerviCore units at one of three times. Either:

a.) as Hammill Manufacturing claims, prior to the first parts being manufactured, the component part manufacturer told Stryker Spine's team the parts could not be made to specification and Stryker Spine's team told Hammill to push forward nonetheless;

b.) also as Hammill Manufacturing claims, Hammill delivered the exact measurements of every batch of parts, including Lot #00105, on Stryker Spine's own inspection sheets, so Stryker Spine could have seen the deviations if it had read and examined the inspection results (as good manufacturing control practices require); or,

c.) Stryker Spine learned of the deviations when it tried to recreate the part at its Cestas, France (in-house) plant and, when unable to recreate the part, realized the earlier parts were made outside specifications.

124. Regardless of when Stryker Spine learned of the defects, it never told Ms. Jaeger or Dr. Zucherman (or, for that matter, any other Study Investigator, the medical community at large, or regulators). To this day, Stryker Spine denies CerviCore parts contain any defects.

VII. CerviCore's Slow-Developing Metallosis

125. Although the CerviCore device appeared to initially meet its endpoint (primarily the increased range of motion), as the years progressed indications of CerviCore's primary danger—its propensity to cause metallosis, metal poisoning, and adverse reactions to the Chromium, Cobalt, Molybdenum, and Titanium debris the device generates—began to emerge.

126. Stryker Spine concealed the danger for a while and continued to push for regulatory approval, but eventually the growing body of evidence showed its device was harmful and it had to abandon the project, never having obtained the regulatory approval it sought.

A. Metallosis from Exposure to Chromium-Cobalt-Molybdenum Wear Debris

127. Manufacturing records show the CerviCore device is made from a mixture of Chromium, Cobalt, and Molybdenum ("Co-Cr-Mo") and that some of its surface is then coated with Titanium spray ("Ti").

128. The articulating surfaces—that is, the portion of the upper and lower units that move against each other—are not Titanium-coated; they are left as Co-Cr-Mo and are designed to be polished to a mirror-like finish to reduce wear.

129. Based on their extensive history with a variety of other medical devices, long before they designed and manufactured CerviCore, Stryker Corporation, Howmedica Osteonics Corporation, and Hammill Manufacturing Corporation knew or should have known:

a.) metal-on-metal medical devices with articulating surfaces generate metal wear debris;

b.) when metal-on-metal articulating surfaces generate wear debris in an implanted medical device, that metal wear debris is released into the patient's bloodstream and/or into the tissue and bone surrounding the device;

c.) improperly-designed metal-on-metal articulating surfaces generate excessive metal wear debris;

d.) improperly-manufactured metal-on-metal articulating surfaces generate excessive wear debris;

e.) any wear debris can adversely affect the implant recipient by causing a wide variety of illnesses, often collectively termed "metallosis," "adverse reactions to metal exposure," "metal poisoning," or "metal hypersensitivity;" and,

f.) metal wear debris has a dose-response relationship (that is, the quantity of debris directly correlates with the severity of the adverse reaction).

130. Stryker Corporation, Howmedica Osteonics Corporation, and Hammill Manufacturing Corporation also knew that allergy to metals is often separate from other adverse reactions to Cr-Co-Mo metal wear debris.

131. Nevertheless, Stryker Spine told Ms. Jaeger and her physician, Dr. Zucherman, that the only risk related to metal exposure was if Ms. Jaeger had a specific allergy to one of the implant metals.

132. In its marketing material, product brochure, informed consent agreement, and in extensive material provided to Dr. Zucherman, other Study Investigators, Study Sites, and the FDA, Stryker Spine said that any person who did not have a metal allergy was a CerviCore candidate.

133. In fact, this is not true. An allergy to a specific metal can cause an adverse reaction, but, metallosis, adverse reactions to metal exposure, metal poisoning, and metal sensitivity can occur even when the patient has no allergy.

134. Furthermore, in enrolling Study Investigators, Study Sites, and patients, Stryker Spine told Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA that CerviCore's rate of metal ion release was negligible as compared to products with a known dangerous rate of release (such as metal-on-metal hips and knees).

135. As medical device manufacturers, Stryker Spine and Hammill Manufacturing are bound by the FDA's Current Good Manufacturing Practices (CGMP) unless, not applicable here, the FDA grants an exemption from a CGMP requirement for purposes of a clinical trial of a new method.

136. Stryker Spine and Hammill Manufacturing also said they would closely monitor their manufacturing and inspection processes to insure quality and safety.

137. However, due to design and manufacturing flaws at both Stryker Spine and Hammill Manufacturing, CerviCore released metal debris at four times the rate Stryker Spine disclosed to Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA.

138. CerviCore's Cr-Co-Mo wear debris caused and/or contributed to Ms. Jaeger's illnesses.

B. Metallosis from Exposure to Sheared-off Titanium Coating

139. Stryker Spine told Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA that it would use a spray of pure Titanium to cover the non-articulating portions of the CerviCore unit in order to promote bony ingrowth.

140. Stryker Spine said its Titanium spray process resulted in a final manufactured part where the Titanium coating adhered to the Cr-Co-Mo base part with a tensile strength that far exceeded the industry standard and completely resisted shear-off.

141. As medical device manufacturers, Stryker Spine and Hammill Manufacturing are bound by the FDA's Current Good Manufacturing Practices (CGMP) unless, not applicable here, the FDA grants an exemption from a CGMP requirement for purposes of a clinical trial of a new method.

142. Stryker Spine and Hammill Manufacturing also said they would closely monitor their manufacturing and inspection processes to insure quality and safety.

143. The Titanium plasma spray process Stryker Spine claims to have used in manufacturing CerviCore devices is controlled by ASTM standards and is refined to the "*per se*" point: that is, defects in a plasma-sprayed Titanium coating are indications the manufacturer failed to implement or follow industry-standard proper manufacturing or inspection processes.

144. At least one explanted CerviCore unit—in the patient for less than a year—shows signs of the Titanium coating shearing off in the patient's body.

145. CerviCore's sheared-off Titanium debris may have also caused and/or contributed to Ms. Jaeger's illnesses.

VIII. Stryker Spine's and Hammill Manufacturing's Fraudulent Concealment

A. Concealment of the Articulating Surface Manufacturing Defect

146. As discussed in Paragraphs 112 to 116, *supra*, after manufacturing the clinical trial devices—including Ms. Jaeger's CerviCore—at Hammill Manufacturing, Stryker Spine transitioned to in-house manufacturing at its Cestas France facility.

147. Initially, when the devices manufactured at Cestas shed four times more metal debris than the Hammill Manufacturing devices, the MPU team questioned Cestas' competence.

148. Soon, though, Stryker Corporation itself adopted the more logical explanation: Hammill's devices had never performed as well as they claimed.

149. Stryker determined Hammill manufactured the CerviCore units outside specifications.

150. Stryker Spine did not tell Ms. Jaeger it learned this.

151. On information and belief, Stryker Spine did not tell Dr. Zucherman or any of its Study Investigators it learned this.

152. Stryker Spine and Hammill Manufacturing actively concealed CerviCore's harmful nature by actively concealing:

a.) that Hammill Manufacturing had manufactured the CerviCore devices outside of specifications at Stryker Spine's instruction unbeknownst to Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA;

b.) that Hammill Manufacturing had altered the CerviCore manufacturing process at Stryker Spine's instruction unbeknownst to Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA;

c.) that, with or without Stryker Spine's knowledge and consent, Hammill Manufacturing had polished CerviCore's articulating surfaces in such a way that the devices shed at least four times more metal wear debris than Stryker Spine and Hamill Manufacturing were telling Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA they shed; and,

B. Concealment of the Titanium Shear-Off Manufacturing Defect

153. Stryker Spine has also learned of at least one instance of an explanted device having indications its Titanium coating sheared off in the patient's body before it was explanted.

154. The process of Titanium plasma spray coating is very well developed and documented.

155. Design and engineering processes exist and are readily known in the medical device manufacturing community.

156. If the proper design and engineering processes are followed, Titanium coating shear-off does not occur.

157. Therefore, any indication of coating shear-off in an explanted device is *per se* evidence of a manufacturing defect.

158. Stryker Spine and Hammill Manufacturing actively concealed CerviCore's harmful nature by actively concealing:

a.) that Hammill Manufacturing and Stryker Spine knew of a design or manufacturing flaw with the Titanium coating process that rendered the CerviCore device more likely to delaminate and release titanium unbeknownst to Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA.

C. Stryker Spine's Adverse Event Manipulation

159. Stryker Spine misled Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA regarding CerviCore's rate of failure.

160. Stryker Spine's primary tool for misreporting CerviCore device failures was a process called "adverse event adjudication."

161. The FDA broadly defines Adverse Events as any untoward patient reaction after receiving either the CerviCore unit or the ACDF. Each Study Investigator reported adverse events to Stryker Spine's Clinical Affairs department.

162. Stryker Spine then "adjudicated" the adverse events and made a determination as to whether those AEs were "serious," "unexpected," and "related to the CerviCore device."

163. Stryker Spine consistently used this process to misreport failure rates by marking adverse events in the CerviCore population as either not serious, not unexpected, or not device-related.

164. Stryker Spine also consistently said it could not reach any conclusion in up to 50% of the adverse events in order to avoid having to deem those events serious, unexpected, and/or device-related

165. Year after year, Stryker Spine completed an annual CerviCore report and distributed it to Study Investigators, including Dr. Zucherman.

166. Year after year, Stryker Spine's CerviCore annual report appeared to show the product was safe and effective and few or no adverse events could be attributed to it.

167. In fact, however, many CerviCore Study Investigators were reporting extensive adverse events that Stryker Spine should have adjudicated as unanticipated, device-related, and/or serious but did not.

168. For example, Stryker Spine adjudicated instances of the CerviCore device shifting in the spine and having to be immediately removed as "not unanticipated." Even though a post-implant device shift is serious (life threatening, even) and obviously device-related, Stryker Spine claimed

that, since it had warned recipients that shifting was a remote possibility, any instance of shifting was "not unanticipated." even though it was serious and device related and even though the rate of shifting was scarily higher than anticipated.

169. In one instance, fellow CerviCore recipient Angela Moneymaker's device shifted within weeks of implant. *Moneymaker v. Howmedica*. Stryker Spine should have stopped the clinical trial immediately to investigate, but it did not.

170. Instead of stopping the study in 2006 before the majority of recipients received the dangerous device, Stryker Spine took four years to fully adjudicate the Angela Moneymaker adverse event. When it finished its determination in 2010, all CerviCore units had been implanted and a proper adjudication could no longer prevent the installation of devices.

171. As another example, at Ms. Jaeger's study site (St. Mary's Hospital in San Francisco), Stryker Spine adjudicated eighteen adverse events, using the process to minimize the device's dangers:

a.) 3 of the 18 AEs were related to the control group (fusion recipients) Stryker Spine fully and properly adjudicated those events as not related to the device;

b.) however, of the 15 AEs reported for CerviCore recipients, it said it reached "no conclusion" on 7 (nearly 50%);

c.) furthermore, when a patient's device migrated three weeks after implant, Stryker Spine adjudicated it as "poor patient selection" rather than a serious, unanticipated, device-related adverse event;

d.) furthermore, when a subject continued to get sicker and asked Stryker Spine to provide for a device explant, Stryker Spine refused and recorded the event as a "consent issue" rather than a serious, unanticipated, device-related adverse event;

e.) in fact, of the fifteen CerviCore Adverse Events at this one Study Site, Stryker Spine only reached a medical conclusion on three;

f.) and, of the three (one explant and fusion, one device migration, and one case of degeneration of the adjacent disc), Stryker Spine did not deem any to be "unanticipated," so it took no action to disclose to the FDA, Study Sites, or Study Investigators that the device presented a danger and patients should be protected.

172. In fact, Ms. Jaeger's own adverse event was never reported to other CerviCore study sites. When her CerviCore unit was finally explanted in 2012 and the cause of the device failure and her sickness was determined to be metallosis caused by the CerviCore device. Because the study had ended and it felt it had not duty to report this event to the FDA, Stryker Spine did not report this event to the Study Investigators either, many of who were still treating very sick CerviCore recipients.

173. During and after the clinical trial, Stryker Spine used the adverse event adjudication process to hide information about CerviCore's dangers from Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA.

174. Dr. Zucherman could have used accurate, truthful information to provide medical care to Ms. Jaeger.

175. On information and belief, if Dr. Zucherman had known that the CerviCore was causing serious, unanticipated adverse events in many of the other 259 recipients, he would have provided different care to Ms. Jaeger as the CerviCore caused to her to get sicker.

176. Stryker Spine actively concealed:

a.) the true rate of device-related adverse events from Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA;

b.) the true rate of serious adverse events from Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA;

c.) the true rate of unanticipated adverse events from Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA; and,

d.) its practices of hiding, mis-classifying, and otherwise minimizing adverse events.

177. Stryker Spine has refused—and continues to refuse—to provide the testing and medical care that would allow Ms. Jaeger, her doctors, and other study participants to know how gravely the CerviCore units have damaged their bodies and, in turn, what medical treatment may be warranted or appropriate.

178. Stryker Spine has refused—and continues to refuse—to provide Ms. Jaeger, her doctors, and other study participants with true and accurate information about their CerviCore units' rate of metal debris shedding, about their CerviCore unit's rate of coating delamination, and about their CerviCore unit's likelihood of causing serious, debilitating illness, particularly over time.

D. Stryker Spine's Misrepresentations to Safety Monitors

179. As a clinical study sponsor, Stryker Spine was statutorily obligated to create a "Data Safety Monitoring Board (DSMB) (sometimes called a "Data Monitoring Committee (DMC)" by the FDA) to oversee safety issues. 21 CFR. § 812.40.

180. DSMBs (DMCs) provide safety data to individual study site IRBs (Institutional Review Boards) which are created at each Study Site to monitor patient safety. IRBs provide safety data to Study Investigators and Study Investigators use that data to care for their patients.

181. Study Investigators rely on the safety data from their IRBs and IRBs rely on the safety data provided by the DSMB (DMC). According to FDA guidance,

> A DMC, on the other hand, generally has access to much more data than the IRB during the trial, including interim efficacy and safety outcomes by treatment arm, and makes recommendations with regard to the entire trial. Given its obligation to minimize the risks to patients, an IRB may take action based on information from any appropriate source, including recommendations from a DMC to the sponsor. A trial may have multiple IRBs, each responsible for the patients at a single site, but only one DMC.

182. Stryker Spine misled its own CerviCore DSMB about CerviCore's safety and about the reasons for the termination of the clinical trial.

183. In updating its DSMB, Stryker Spine blamed CerviCore's demise on "business and economic reasons" as well as how "difficult" the FDA made it to obtain approval. As late as January 2012, Stryker Spine was still misleading the DSMB:

> The board members and Dr. Berry expressed disappointment that Stryker is choosing to give up on the [CerviCore] program when the efficacy analysis was positive and the endpoints were met. Dr. Berry asked Stryker to explain the decision to stop the study now.
>
> Stryker advised that upper management decided for business and economic reasons to withdraw the PMA. It was mainly due to the lack of insurance reimbursement for the patients but also the uncertainty of approval. The PMA has been with the FDA for almost 3 years and they raised continuous questions, so the company felt it was not a good business decision to continue.
>
> * * *
>
> The DSMB and Dr. Berry felt it was very unfortunate that the FDA made it so difficult.

184. Stryker Spine's DSMB, having been provided false information by the study sponsor, passed on this same faulty information to the St. Mary's Medical Center IRB.

185. This lacking, false, and faulty safety information deprived Dr. Zucherman of the ability to provide appropriate, informed medical care to Ms. Jaeger.

E. Stryker Spine's and Hammill Manufacturing's Present Day Concealment

186. On information and belief, Hammill Manufacturing must have known it was manufacturing the CerviCore units outside of specifications.

187. Therefore, either:

a.) Hammill Manufacturing deviated from specifications and chose not to tell its customer, Stryker Spine, in which case Stryker Spine did not find out about the manufacturing defects until around 2010 when it tried to recreate the parts in Cestas;

b.) some Stryker Spine MPU employee instructed Hammill Manufacturing to deviate, making Stryker Spine vicariously liable for the choice to deviate; or,

c.) Stryker Spine's management instructed Hammill Manufacturing to deviate, making Stryker Spine fully liable for the choice.

188. In any case, Stryker Spine has known of the manufacturing deviations since at least 2010 and has hid them.

189. In fact, the accusations of deviations were central to three years of litigation between CerviCore's inventors (Dr. and Mr. Errico) and Stryker Corporation spanning 2010 to 2013 and litigated in three separate courts.

190. Yet, Stryker Spine has never told Ms. Jaeger it knows her CerviCore device contains manufacturing defects. Ms. Jaeger first learned this in or around late 2015.

191. In fact, Ms. Jaeger first learned of the cause of her metal poisoning in or around late 2015.

192. Stryker Spine has never told Ms. Jaeger that when it tried to recreate CerviCore devices the way Hammill Manufacturing created hers, it found they shed four times the metal debris they claimed. Ms. Jaeger first learned this in or around late 2015.

193. Stryker Spine has never told Ms. Jaeger that its CerviCore devices contain a manufacturing defect indicated by coating shear-off. Ms. Jaeger first learned this in or around late 2015.

194. Even after making the affirmative promise to Ms. Jaeger that it would provide her with good and bad information about the CerviCore as it learned it, Stryker Spine has never told Ms. Jaeger that physicians are reporting an alarming number of adverse events, but Stryker Spine is using an adjudication process to minimize and conceal these. Ms. Jaeger first learned this in or around late 2015.

195. Ms. Jaeger is not the only victim of Stryker Spine's fraudulent concealment To date, fourteen CerviCore clinical trial participants have now filed suit asking courts to hold CerviCore's manufacturers responsible.

196. In 2009, at Stryker Spine's behest (and using data Stryker Spine provided him), Principal Study Investigator Dr. Jeffrey Fischgrund published an article in which he said CerviCore had "a

history of safety and proven durability with low metal ion release and wear rates." Stryker Spine had not told him it had information belying this.

197. And, in 2011, Dr. Fischgrund testified in a deposition on Stryker Spine's behalf in the Errico litigation. His testimony demonstrates Stryker Spine was actively concealing the dangers even from its own Principal Study Investigator:

a.) When asked to read the FDA's "not-approvable" letter and comment on why the FDA determined the device could not be approved, Dr. Fischgrund had to admit he was not aware—until that moment in the deposition—that the device had had more revisions and explants than expected.

b.) When the questioner confronted him with a 6.5% explant rate, Dr. Fischgrund indicated some level of surprise: "It's just a higher number than I would have anticipated." And, when asked to compare the rate of explants to other studies, he said "I know this is higher than other studies I've seen."

c.) When asked if he was informing his patients of any concerns about metal-on-metal exposure because of the CerviCore, Dr. Fischgrund said some patients had asked about it, but he told them that metal ion release had "not caused any clinical problems that we know of." On information and belief, this is because Stryker Spine had not informed Dr. Fischgrund—or any Study Investigator—of the dire metal-on-metal concerns.

198. On information and belief, Stryker Spine has not only concealed the negative information from Ms. Jaeger and the other CerviCore recipients, it has also concealed the information from its Study Investigators, including Dr. Zucherman.

IX. Stryker Spine's Breach of its Contractual and Moral Duties

A. Stryker Spine's Breached Duty to Protect Patients from Later Dangers

199. Even if Stryker Spine and Hammill Manufacturing could show they were completely unaware of CerviCore's dangers when Stryker Spine began the human clinical trial, they became

aware of CerviCore's grave dangers at some point during the study period and abandoned Ms. Jaeger and her fellow CerviCore study participants.

200. Five years into the human clinical trial, Stryker Spine had repeatedly tried to convince the FDA to grant it commercial approval to market CerviCore and the FDA had consistently said "no," finally determining the device was "not approvable."

201. Determined to capitalize on its $200 million investment, Stryker Spine returned to the CerviCore recipients and asked them to extend their participation in the study from the original five years to eight years.

202. Around this time, CerviCore recipients like Ms. Jaeger were starting to show signs of serious illness from the device and Study Investigators like Dr. Zucherman were starting to report a growing number of signs of device-caused metallosis.

203. Undeterred, Stryker Spine cajoled some patients into signing the study extension forms, but actively excluded some of the sickest patients to protect their study related data. In some cases, Stryker Spine representatives became very aggressive with clinical trial participants, repeatedly calling them at home and repeatedly threatening them with removal of access to their physicians and the healthcare services they now needed.

204. In other cases—presumably when representatives deemed a study subject more likely to report an adverse event—Stryker Spine quickly removed certain people from the clinical trial, saying they had "withdrawn" if they missed one appointment or had questions about the new forms they were required to sign. This was the case with Ms. Jaeger: Stryker Spine dropped her out of the CerviCore study months before her explant surgery, possibly because it saw the dim prospects and wanted to avoid reporting another in-study event.

205. Then, having obtained approval to extend the study to eight years, Stryker Spine abandoned the CerviCore product because it realized it was commercially unfeasible due primarily to its potential for causing metal poisoning.

206. Stryker Spine instructed each of its Study Investigator to send a form letter to those CerviCore recipients who, at that point, remained in the study.

207. Those CerviCore recipients who Stryker Spine had previously removed from the study—whether because the patient had complained, because the patient had adverse reactions Stryker Spine did not want to report, because the patient would not sign additional releases, or for other reasons—did not receive a notice of the study's termination and Stryker Spine's abandonment of the CerviCore product.

208. Stryker Spine had to seek FDA approval to terminate the clinical trial while most of the 260 CerviCore recipients still had the device in their spines.

209. In 2012, the FDA rejected Stryker Spine's attempt to close the clinical trial, determining Stryker Spine had not properly informed CerviCore recipients and their physicians (such as Ms. Jaeger and her Study Investigator, Dr. Zucherman) of CerviCore's dangerous propensity to release metal debris and cause metallosis.

210. Furthermore, the FDA rejected Stryker Spine's attempt to close the clinical trial because it had not provided an adequate plan for tracking and reporting adverse events in the population who still had the device implanted.

211. Stryker Spine only obtained FDA approval to terminate the clinical trial when it told the FDA it would disclose the known risks related to metal debris.

212. At this point, however, Stryker Spine had already sent its study closing letter to CerviCore recipients and thereafter cut off contact with Ms. Jaeger and other study participants. Stryker Spine never provided Ms. Jaeger with the information it promised it would provide.

213. Stryker Spine has never provided Ms. Jaeger or other study participants with accurate information about what is in their bodies, the dangers their doctors need to watch for and treat for, and other information it knows that might help Ms. Jaeger and other study participants recover from the damage CerviCore caused.

214. Furthermore, after promising the FDA it would record and manage post-study adverse events, and after telling Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, and safety personnel at other Study Sites how it would manage this information, Stryker Spine secretly changed its mind and decided not to provide its adverse event information. But, it never told Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other Study Investigators, safety personnel at St. Mary's Medical Center, and safety personnel at other Study Sites of this change.

215. Thus, whether or not Stryker Spine and Hammill Manufacturing were aware of CerviCore's dangers when Stryker Spine began the human clinical trial, they became aware of CerviCore's grave dangers at some point during the study period and abandoned Ms. Jaeger and her fellow CerviCore study participants, causing considerable further harm.

B. <u>The Consent Agreement – Failure to Provide Medical Care</u>

216. Stryker Spine created an Informed Consent agreement and provided it to safety personnel at St. Mary's Medical Center as well as safety personnel at other Study Sites for their use in enrolling patients in the CerviCore clinical trial.

217. Each CerviCore patient signed Stryker Spine's "RESEARCH SUBJECT INFORMATION AND CONSENT FORM" purporting to be an informed consent to participate in the human clinical trial of CerviCore.

218. The document Stryker Spine provided contained the following term:

> Medical treatment will be offered if you experience a complication or injury as a result of your participation in the clinical study. You (or your insurance carrier) will be financially responsible for costs to treat a research-related complication or injury. The study Sponsor [Stryker Spine] will reimburse the hospital and/or your study doctor for costs for necessary medical treatment for an injury or complication you experience that is solely as a direct result of the use of a CerviCore implant according to the study protocol and the costs for medical treatment are not covered by any responsible third party payer and are not attributable to negligence or misconduct by you, the hospital, or the study doctor.

219. In addition to the initial Informed Consent template, Stryker Spine provided St. Mary's Medical Center and other Study Sites with a 2010 addendum that reinforced its obligations:

> Medical treatment will be offered if you experience a complication or injury as a result of your participation in the clinical study. If it is determined by the Principal Investigator that the CerviCore device must be removed, the study Sponsor will cover the cost of the explant surgery if the explant surgery is performed at the Institution. You (or your insurance carrier) will be responsible for costs to treat a research related complication or injury, including a complication or injury resulting from an explant surgery, unless the complication or injury is directly related to the CerviCore device and is treated at the Institution. In this case, the study sponsor will cover the cost of treating the complications or injury. The study sponsor will not provide any other form of compensation for injury.

220. Stryker Spine field representatives coerced patients to sign this agreement, particularly with the threat that they would not be able to see their study doctor for further care if they did not enter the agreement.

221. Elsewhere, the agreement assures the signer:

> By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

222. Ms. Jaeger understood these promises as well as other communication related to the CerviCore clinical trial to mean Stryker Spine would provide her with medical care—including, diagnosis, testing, and surgical intervention, if necessary—should the CerviCore device cause her medical problems.

223. Stryker Spine has breached this promise.

224. Numerous CerviCore patients like Ms. Jaeger have had devices fail and have had other complications and injuries resulting from the CerviCore device.

225. Stryker Spine, however, has repeatedly refused to offer medical treatment.

226. Ms. Jaeger is very fortunate that Dr. Zucherman still sees her, although outside the study and without the reimbursements from Stryker Spine.

227. Some study investigators will not see CerviCore patients who do not have insurance. On information and belief, this is because Stryker Spine refuses to offer medical care and refuses to reimburse doctors for the treatment patients need.

228. Some study investigators will not see CerviCore patients who have Medicaid or sub-standard insurance. On information and belief, this is because Stryker Spine refuses to offer medical care and refuses to reimburse doctors for the treatment patients need.

229. Whether or not patients signed the Informed Consent or the addenda to that, Stryker Spine refused medical care and refused compensation.

C. The Consent Agreement – Failure to Provide "New Information"

230. Stryker Spine's Informed Consent template provided to St. Mary's Medical Center and other Study Sites also promised Ms. Jaeger and other CerviCore recipients:

> NEW INFORMATION
>
> During the course of the study you will be informed of any important new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the study or new alternatives to participation that may change your decision to be in this study. If new information is provided to you, you will be asked to give written consent to continue participating in the study.

231. As the study was under way, Stryker Spine knew of a growing body of dangers posed by CerviCore.

232. Yet, never once did Stryker Spine inform Ms. Jaeger or her fellow CerviCore study participants of any "important new findings (either good or bad)."

233. In fact, in the face of a mounting body of evidence about CerviCore's dangers, Stryker Spine denied anything was wrong with the CerviCore device and actively tried to isolate victims of its clinical trial and convince them their problems were self-induced and idiosyncratic.

X. Causes Of Action

First Cause of Action
Design Defect

234. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

235. Stryker Spine is a "Manufacturer" in that it designed, produced, made, fabricated, and introduced into the stream of commerce CerviCore.

236. Stryker Spine has a duty to design, manufacture, test, market, advertise, label, distribute, and sell CerviCore so that it was reasonably safe for its foreseeable use.

237. Ms. Jaeger's use of CerviCore as a cervical implant—and, for that matter, each human subject's use of CerviCore as a cervical implant—was not only anticipated by Stryker, but, in fact, was precisely solicited by Stryker Spine.

238. Due to design defects, CerviCore is unreasonably dangerous in that:

a.) its metal-on-metal articulating design causes the release of dangerous metal debris as the two all-metal pieces abrade on each other;

b.) its Titanium coating has a tendency to delaminate and release metal ions into the bloodstream and surrounding tissue; and,

c.) its various manufacturing processes are improperly designed such that they lead to a device that is more likely to shed metal debris.

239. CerviCore's design defects caused Ms. Jaeger's injuries and there is no other reasonable, secondary cause of her injuries.

240. CerviCore's design is defective in that, when it left Stryker Spine's control, it was more dangerous than an ordinary consumer would expect when used in its intended or reasonably foreseeable manner.

241. CerviCore's design is defective in that, when it left Stryker Spine's control, its known, knowable, and/or foreseeable risks outweighed any potential benefit it might provide.

242. CerviCore's design is defective in that, when it left Stryker Spine's control, it was more dangerous than necessary, as evidenced by the extensive set of competing, but less dangerous, alternatives.

243. CerviCore's dangers are so great that reasonable health care professionals, including Dr. Zucherman, would not prescribe its use if they knew of CerviCore's true nature.

244. CerviCore's dangers are so great that reasonable consumers in general—and Ms. Jaeger and her fellow CerviCore study participants in specific—would not have allowed its implantation if they knew of CerviCore's true nature.

245. Stryker Spine knew or should have known of CerviCore's dangers; knew or should have known of safer alternatives; and disregarded the risks to Ms. Jaeger and other CerviCore recipients.

246. Stryker Spine is liable under New Jersey law and California law for its negligent acts leading to CerviCore's design defects.

247. Furthermore, Stryker Spine is strictly liable under New Jersey law and California law for CerviCore's design defects and the injuries they caused.

248. As a direct and proximate result of Stryker Spine's wrongful actions, Ms. Jaeger suffers from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs Colleen Jaeger and William Jaeger demand judgment against Defendant Howmedica Osteonics Corp. for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Second Cause of Action
Manufacturing Defect

249. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

250. Stryker Spine is a "Manufacturer" in that it designed, produced, made, fabricated, and introduced into the stream of commerce CerviCore.

251. Stryker Spine has a duty to design, manufacture, test, market, advertise, label, distribute, and sell CerviCore so that it was reasonably safe for its foreseeable use.

252. Ms. Jaeger's use of CerviCore as a cervical implant—and, for that matter, each human subject's use of CerviCore as a cervical implant—was not only anticipated by Stryker Spine, but, in fact, was precisely solicited by Stryker Spine.

253. As detailed throughout, Hammill Manufacturing manufactured CerviCore units—particularly the articulating surfaces of those units—outside specifications, at the instruction of—or at least with the knowledge of—Stryker Spine.

254. Furthermore, as detailed throughout, Stryker Spine deviated from manufacturing principles as evidence by indications of CerviCore coating delamination.

255. Due to manufacturing defects, at the time CerviCore left the control of Stryker Spine and entered the stream of commerce, it contained one or more conditions that rendered it defective and unreasonably dangerous in light of its nature and intended use.

256. These manufacturing defects made CerviCore more dangerous than an ordinary consumer would expect when used in its intended or reasonably foreseeable manner.

257. These manufacturing defects made CerviCore known, knowable, and/or foreseeable risks outweigh any potential benefit it might provide.

258. These manufacturing defects made CerviCore more dangerous than necessary, as evidenced by the extensive set of competing, but less dangerous, alternatives.

259. CerviCore's dangers are so great that reasonable health care professionals, including Dr. Zucherman, would not prescribe its use if they knew of CerviCore's true nature.

260. CerviCore's dangers are so great that reasonable consumers in general—and Ms. Jaeger and her fellow CerviCore study participants in specific—would not have allowed its implantation if they knew of CerviCore's true nature.

261. Stryker Spine knew or should have known of CerviCore's dangers; knew or should have known of safer alternatives; and disregarded the risks to Ms. Jaeger and other CerviCore recipients.

262. Stryker Spine is liable under New Jersey law and California law for its negligent acts leading to CerviCore's manufacturing defects.

263. Furthermore, Stryker Spine is strictly liable under New Jersey law and California law for CerviCore's manufacturing defects and the injuries they caused.

264. As a direct and proximate result of Stryker Spine's wrongful actions, Ms. Jaeger suffers from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs Colleen Jaeger and William Jaeger demand judgment against Defendant Howmedica Osteonics Corp. for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Third Cause of Action
Failure to Warn

265. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

266. Alternatively or additionally, CerviCore was defective because Stryker Spine failed to properly label, market, and warn human study subjects and/or their physicians of its risks and adverse events.

267. Stryker Spine knew of multiple dangers with CerviCore, including that it might not implant properly, that its design caused excessive wear, that it was prone to breaking down prematurely, that it was prone to delaminating, that they manufactured it using improper processes, that they manufactured it in a facility prone to contamination, that it was made from cobalt, chromium, molybdenum, and titanium, and that it was likely to cause metallosis.

268. Furthermore, as detailed throughout, Stryker Spine had a statutorily-created duty to warn the CerviCore Data Safety Monitoring Board (DSMB) by providing accurate safety information to the DSMB so the DSMB could inform IRBs of CerviCore's dangers.

269. Furthermore, as detailed throughout, the FDA created an explicit duty to warn when it instructed Stryker Spine to inform patients of CerviCore's potential to cause metallosis and adverse local tissue reactions (ATLRs).

270. Stryker Spine did not adequately warn Ms. Jaeger of these and other dangers. This shortcoming left Ms. Jaeger incapable of making informed choices and granting informed consent.

271. Furthermore, Stryker Spine failed to properly warn Plaintiffs, the public, and the medical community at large by not properly posting adverse events.

272. Stryker Spine's failure to warn caused the initial harm:

a.) had Ms. Jaeger known of CerviCore's potential for causing deleterious, permanent harm, and/or of the adverse events, Ms. Jaeger would not have allowed the device to be implanted in her body.

273. Furthermore, Stryker Spine's failure to warn worsened Ms. Jaeger's harm and caused ongoing harm:

a.) had Ms. Jaeger known of CerviCore's dangers even after implant, she could have sought and received medical care, monitoring, explant, other care.

b.) had Ms. Jaeger known of the safety data that Stryker Spine manipulated and concealed during the clinical trial, she could have sought and received medical care, monitoring, explant, and other care.

274. Stryker Spine is liable under New Jersey law and California law for its negligent acts in failing to warn Ms. Jaeger of CerviCore's true dangers.

275. Furthermore, Stryker Spine is strictly liable under New Jersey law, and California law for failing to warn Ms. Jaeger of CerviCore's true dangers.

276. As a direct and proximate result of Stryker Spine's wrongful actions, Ms. Jaeger suffers from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs Colleen Jaeger and William Jaeger demand judgment against Howmedica Osteonics Corporation for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Fourth Cause of Action
Fraud

277. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

278. Through its initial reports on the CerviCore device and through its annual reports on the CerviCore device, Stryker Spine actively and fraudulently misrepresented CerviCore's safety profile to regulators, to physicians, to safety boards, and, by proxy, to patients.

279. Through manipulation of the adverse event adjudication process, Stryker Spine actively and fraudulently manipulated the safety data (adverse events) reported in CerviCore patients to regulators, to physicians, to safety boards, and, by proxy, to patients.

280. By publicly saying they had followed proper manufacturing protocols when, in fact, they had not, Stryker Spine actively and fraudulently misrepresented the ultimate safety of the CerviCore devices.

281. Furthermore, Stryker Spine had a duty to disclose certain concealed facts, which include:

a.) the true risks and dangers posed by CerviCore

b.) their deviation from manufacturing specifications

c.) the indications of manufacturing defects shown by the CerviCore Titanium coating shearing off in the body;

d.) the adverse events resulting from CerviCore; and,

e.) other negative information about CerviCore.

282. In violation of their duties to disclose facts about the dangerous device, Stryker Spine concealed this information from Ms. Jaeger, other CerviCore recipients, Dr. Zucherman, other

Study Investigators, safety personnel at St. Mary's Medical Center, safety personnel at other Study Sites, and the FDA.

283. Stryker Spine's fraud caused the initial harm:

a.) had Ms. Jaeger known of Stryker Spine's and Hammill Manufacturing's mistakes and intentional acts leading to CerviCore's potential for causing deleterious, permanent harm; of the fact that Stryker Spine was operating the study outside the scope of any regulatory approval it received; and/or of the adverse events, she would not have allowed the device to be implanted in her cervical spine.

284. Furthermore, Stryker Spine's fraud worsened Ms. Jaeger's harm and caused ongoing harm:

a.) had Ms. Jaeger known that Stryker Spine and Hammill Manufacturing committed mistakes and intentional acts that led to CerviCore to generate metal debris even after implantation, she could have sought and received medical care, monitoring, explant, other care.

b.) had Ms. Jaeger known of the safety data that Stryker Spine manipulated and concealed during the clinical trial, she could have sought and received medical care, monitoring, explant, and other care.

285. As a direct and proximate result of Stryker Spine's wrongful actions, Ms. Jaeger suffers from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs Colleen Jaeger and William Jaeger demand judgment against Defendant Howmedica Osteonics Corp. for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Fifth Cause of Action
Breach of Contract and Ethical Duties

286. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

287. Stryker Spine drafted informed consent agreements and required its Study Investigators to enter into the agreements with patients, including Ms. Jaeger.

288. Stryker Spine's agreements bind Stryker Spine—as the Study Sponsor—to certain contractual and ethical duties.

289. When it failed to provide Ms. Jaeger with necessary medical care, Stryker Spine breached its contractual duties and ethical duties.

290. When it failed to continue monitoring the study participants and their health, Stryker Spine breached its contractual duties and ethical duties.

291. When it failed to provide Ms. Jaeger with all the information it knew of CerviCore's dangers, it deprived Ms. Jaeger of the ability to make informed choices about her healthcare, both before joining the study and at every time since.

292. When it failed to provide Ms. Jaeger with all the information it knew of CerviCore's dangers, Stryker Spine breached its contractual and ethical duties.

WHEREFORE, Plaintiffs Colleen Jaeger and William Jaeger demand judgment against Howmedica Osteonics Corporation for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Sixth Cause of Action
Breach of Warranty

293. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

294. By introducing CerviCore into the stream of commerce, Stryker Spine impliedly warranted the product was merchantable, including: that CerviCore would pass without objection in the trade; that it would be of average quality; that it would be fit for its ordinary purpose and use; that it would be packaged and labeled properly; and that it would conform to the promises made in the marketing, packaging, and labeling of the product (including those promises made as part of the study).

295. As a medical device manufacturer, Stryker Spine is bound by the FDA's Current Good Manufacturing Processes (CGMP) unless the FDA explicitly grants them an exception (which is not applicable here). The CGMP create the standard of care for medical device manufacturers.

296. Ms. Jaeger and other CerviCore recipients relied on these warranties when agreeing to be a part of the CerviCore study and would not have become a part of the study if they knew any of these was false.

297. As detailed throughout, Stryker Spine breached each of these warranties.

298. Furthermore, through its Informed Consent Agreements and through other communication, Stryker Spine expressly warranted to Ms. Jaeger:

a.) that it had designed and manufactured the CerviCore devices safely and according to the law, including by following Current Good Manufacturing Practices;

b.) that it had obtained proper regulatory approval to conduct a study on human subjects and were operating the studies within the scope of that;

c.) that the study was in compliance with state law;

d.) that the study was following certain specific protocols;

e.) that "Medical treatment will be offered if you experience a complication or injury as a result of your participation in the clinical study";

f.) that, by including it with the consent agreement, Stryker Spine would honor the Medical Research Subject's Bill of Rights; and,

g.) that it would provide Ms. Jaeger with updated information throughout the study.

299. As a direct and proximate result of Stryker Spine's wrongful actions, Ms. Jaeger suffers from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs Colleen Jaeger and William Jaeger demand judgment against Defendant Howmedica Osteonics Corp. for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Seventh Cause of Action
Infliction of Emotional Distress

300. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

301. Stryker Spine acted in an extreme and outrageous manner in a variety of ways, including by concealing and ignoring CerviCore's risks, by concealing, ignoring, and refusing to correct repeated deficiencies in their manufacturing processes, by misleading Ms. Jaeger and other CerviCore recipients about design and manufacturing defects in CerviCore, by misleading them about Stryker Spine's commitment to care for their health, and by not actually providing follow-up care as promised.

302. Stryker Spine should have known and/or did know that their conduct could cause and would cause emotional distress the study participants and their families.

303. CerviCore caused illness and bodily harm to Ms. Jaeger, caused metallosis, which includes many detrimental effects on the brain, caused pain and suffering, caused loss of enjoyment of life, and caused the risk of shortened life span. These conditions, directly and indirectly caused emotional distress to Ms. Jaeger and to all CerviCore recipients.

304. Stryker Spine intentionally caused, or recklessly disregarded the risks of causing, this emotional distress.

305. Alternatively, Stryker Spine was negligent in causing Ms. Jaeger's emotional distress

306. As a direct and proximate result of Spine's wrongful actions, Ms. Jaeger suffers from emotional distress.

WHEREFORE, Plaintiffs Colleen Jaeger and William Jaeger demand judgment against Defendant Howmedica Osteonics Corp. for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Eighth Cause of Action
Loss of Consortium

307. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

308. Ms. Jaeger and other study subjects who received CerviCore units have endured permanent, profound, and debilitating physical, emotional, and mental suffering.

309. These illnesses have diminished and deprived Ms. Jaeger's spouse, Mr. Jaeger, of her services, companionship, and society. Furthermore, they likely will diminish and deprive their services, companionship, and society for the remainder of their lives.

310. As a direct and proximate result of Stryker Spine's wrongful actions, Mr. Jaeger suffers from a loss of consortium.

311. As a direct and proximate result of Stryker Spine's wrongful actions, Ms. Jaeger suffers from the serious medical conditions alleged herein and that has caused Mr. Jaeger to suffer a loss of consortium.

WHEREFORE, Plaintiffs Colleen Jaeger and William Jaeger demand judgment against Defendant Howmedica Osteonics Corp. for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Punitive Damages Allegations

312. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

313. Prior to some or all of the CerviCore implantations, Stryker Spine knew the CerviCore units:

a.) were not manufactured as designed,

b.) were not manufactured as they told the FDA they were,

c.) were not manufactured safely and in a sanitary way,

d.) were made to withstand articulation,

e.) were made such that articulation caused excessive metal debris,

f.) were made such that the coating delaminated in the body,

g.) were made from metals that cause metallosis and other adverse reactions, and

h.) were dangerous to the human victims into whom they were implanted.

314. Prior to some or all of the CerviCore implantations, Stryker Spine knew of one or more CerviCore failures but failed to properly report and/or disclose this.

315. These acts, conduct, and omissions of Stryker Spine, as alleged throughout this Complaint, were willful and malicious. Stryker Spine committed these acts with a conscious disregard for the rights of Ms. Jaeger and other CerviCore victims and for the primary purpose of increasing profits from the future sales of CerviCore. Stryker Spine's outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against each in an amount appropriate to punish and make an example of them.

316. Stryker Spine, through its past and present officers, directors, managers, and agents, knew CerviCore was dangerous and presented a substantial and unreasonable risk of harm to Ms. Jaeger and other CerviCore victims but hid this and pushed forward with trials on human victims nonetheless.

317. Stryker Spine's conduct was so despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Stryker Spine and Hammill Manufacturing with willful and conscious disregard for the safety of Ms. Jaeger and other CerviCore victims, entitling Plaintiffs to punitive and exemplary damages.

Prayer for Relief

WHEREFORE, Plaintiffs Colleen Jaeger and William Jaeger pray for judgment against Defendant Howmedica Osteonics Corp., as follows, as appropriate to each cause of action alleged:

A. General damages in an amount that will conform to proof at time of trial;

B. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;

C. Loss of earnings and impaired earning capacity according to proof at the time of trial;

D. Medical expenses, past and future, according to proof at the time of trial;

E. Past and future mental and emotional distress, according to proof;

F. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;

G. Punitive or exemplary damages according to proof;

H. Restitution, disgorgement of profits, and other equitable relief;

I. Injunctive relief;

J. Attorneys' fees;

K. Costs of suit incurred herein;

L. Pre-judgment interest as provided by law; and

M. Such other and further relief as the Court may deem just and proper.

Demand for Jury Trial

Plaintiffs hereby demands a jury trial on all claims so triable in this action.

March 15, 2016.

Respectfully Submitted,

/s/ James G. O'Brien

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Counsel for Plaintiffs Colleen Jaeger and William Jaeger

CERTIFICATE OF SERVICE

I certify a true and accurate copy of the foregoing was filed through the Court's electronic CM/ECF system on this date and that all parties of record may access the filing through that system.

March 15, 2016.

/s/ James G. O'Brien
James G. O'Brien (SBN 308239)